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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/054,447 | 01/22/2002 | James R. Keogh | P-9170.00 | 5485 |
| 27581 | 7590 | 06/05/2007 | | |
| MEDTRONIC, INC. 710 MEDTRONIC PARKWAY NE MINNEAPOLIS, MN 55432-9924 | | | EXAMINER HAGOPIAN, CASEY SHEA | |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1615 | |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| | | | | |
|------------------------------|-----------------|--|--------------|--|
| Office Action Summary | Application No. | | Applicant(s) | |
| | 10/054,447 | | KEOGH ET AL. | |
| | Examiner | | Art Unit | |
| | Casey Hagopian | | 1615 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05 March 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10,233 and 273-281 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,7,9,10,233,273-276,278,280 and 281 is/are rejected.
- 7) ☒ Claim(s) 6,8,277 and 279 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of applicant's Amendment/Remarks filed 3/5/2007.

Currently, claims 1-10, 233, 273-281 are pending. Claims 1, 5 and 276 have been amended and claims 52-61, 103-114, 162-173, 234-243, 246-249, 255-261, 264-267 and 282-292 have been cancelled.

MAINTAINED REJECTIONS

Claim Rejections - 35 USC § 112, 2nd paragraph

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 1 and its depending claims 2-10, 276, 280 and 281 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 contains the method step of coating the medical device with a hydrophilic polymer. **It is unclear as to when the catechol is disposed on the surface of the device, when the chemical bond is formed and whether the catechol is disposed on the surface of the device separately from the hydrophilic polymer or if it is included in for instance, a composition comprising the hydrophilic polymer and guanidino moiety and then disposed on the surface of the device.** Appropriate correction is respectfully requested.

As discussed above, it is unclear in claim 1 whether the catechol is disposed onto the surface of the medical device separately from the hydrophilic polymer because

Art Unit: 1615

the claim lacks a method step that clearly point out when the catechol is disposed onto the surface. Accordingly, claims 9, 10, 280 and 281 complicate the issue further. If claims 1 and 233 intend for a catechol to be disposed onto the surface prior to the application of the hydrophilic polymer, then claims 9, 10, 280 and 281 do not appear to further limit the claim. Appropriate correction/clarification is respectfully requested.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-5, 7, 9, 10, 233, 273-276, 278, 280 and 281 are rejected under 35 U.S.C. 102(e) as being anticipated by Sawhney (USPN 6,818,018 B1). In light of broadly written claim 1 and the rejection under 35 USC 112, 2nd paragraph the examiner is giving the claims the broadest reasonable interpretation. As such, the examiner is interpreting claim 1 in such a way that allows for a composition comprising a catechol and a hydrophilic polymer containing a guanidino moiety that is coated on a medical device. Inherently, said composition would dispose a catechol on the surface of the device and a chemical bond would form between the catechol and guanidino moiety. With that in mind, Sawhney discloses compositions and methods for forming hydrogels

for the use of medical device coatings (abstract). More specifically, Sawhney discloses that the compositions include preferred water-soluble polymers including polyguanidine (column 12, lines 18-21) and bioactive species including the specific catechol, dopamine (column 17, line 46). Sawhney also discloses that the bioactive can be contained in a secondary coating (column 16, lines 2-4). Sawhney further discloses particular medical devices, including catheters, cannulas, bone prostheses, minipumps, platinum wires and so on (column 18, lines 26-36). Sawhney also contemplates primers, for example, to establish a mechanical or chemical linkage with the underlying surface (column 22, lines 22-30). Thus, the disclosures of Sawhney render the instant claims anticipated.

Claim Objections

Claims 6, 8, 277 and 279 are objected to as being dependent upon a rejected base claim.

Response to Arguments

Applicant's amendment/arguments regarding the rejection of claims 1-10, 276, 280 and 281 under 35 USC 112, 2nd paragraph have been fully considered but they are unpersuasive. Applicant's amendment does not clarify the matters that the examiner pointed out in the Office Action dated 12/04/2006. It remains unclear as to when the catechol is disposed on the surface of the device, when the chemical bond is formed and whether the catechol is disposed on the surface of the device separately from the hydrophilic polymer or if it is included in for instance, a composition comprising the

hydrophilic polymer and guanidino moiety and then disposed on the surface of the device. Also, regarding the “primer” of claims 9, 10, 280 and 281 and more specifically “the primer comprises the catechol moiety”, it is not clear how the limitation in the independent claims, “a catechol moiety disposed on the surface of the device” is different from “a primer” or “a primer comprises the catechol moiety”. In both instances, the claim language currently allows for multiple interpretations and as such the rejection of claims 1-10, 276, 280 and 281 under 35 USC 112, 2nd paragraph is maintained.

Applicant's amendment regarding claims 5 and 276 render the rejection under 35 USC 112 moot. Thus, the rejection of claims 5 and 276 under 35 USC 112, 2nd paragraph is withdrawn.

Applicant's arguments with regards to the rejection of the claims under 35 USC 102 have been fully considered but are unpersuasive. Applicant's point out that Sawhney is not available as prior art under 35 USC 102(b). The examiner thanks applicants for their careful consideration of the prior art. The examiner has modified the rejection to a 102(e) rejection. The substance of the rejection itself has not changed, thus the rejection is being maintained. In regards to applicant's arguments, applicant asserts that Sawhney does not disclose a hydrogel formed from a polyguanidine polymer that includes a bioactive agent, much less dopamine. In response, the examiner respectfully disagrees with applicant's rationale. The MPEP states, “patents are relevant as prior art for all they contain” including “non-preferred and alternative embodiments” (MPEP 2123). As discussed in the rejection dated 12/4/2006, Sawhney generally teaches hydrogels comprising a bioactive agent for the use in medical

Art Unit: 1615

devices. Sawhney also teaches the preferred hydrogel material being poly(guanidine) as well as the bioactive agent, dopamine. Thus, Sawhney teaches the claimed invention and as such the rejection of the claims under 35 USC 102 is maintained.

Conclusion

All claims have been rejected/objected to; no claims are allowed.

Correspondence

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Casey Hagopian whose telephone number is 571-272-6097. The examiner can normally be reached on Monday through Friday from 7:00 am to 4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Carlos Azpuru, can be reached at 571-272-0588. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Art Unit: 1615

Casey Hagopian

Casey Hagopian
Examiner
Art Unit 1615

Carlos A. Azpuru
CARLOS A. AZPURU
PRIMARY EXAMINER
GROUP 1500